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| 10/817,490 | 04/02/2004 | Hsing-Pang Hsieh | 70001-021001 | 2330 |
| 69713 7590 11/06/2009 OCCHIUTI ROHLICEK & TSAO, LLP 10 FAWCETT STREET CAMBRIDGE, MA 02138 | | | | |
| EXAMINER CHONG, YONG SOO | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1627 | | | | |
| NOTIFICATION DATE | | DELIVERY MODE | | |
| 11/06/2009 | | ELECTRONIC | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

INFO@ORTPATENT.COM

Advisory Action
Before the Filing of an Appeal Brief

Application No.

10/817,490

Applicant(s)

HSIEH ET AL.

Examiner

Yong S. Chong

Art Unit

1627

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 20 October 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: _____.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☒ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Yong S. Chong/
Primary Examiner, Art Unit 1627

Continuation of 11, does NOT place the application in condition for allowance because:

Applicant's arguments have been fully considered but found not persuasive for reasons of record. Applicant argues that Hwang does not teach treating HCV infection and Baba does not teach the claimed sesquiterpene lactone compound.

In response to applicant's arguments against the references, one cannot show nonobviousness by attacking references individually where the rejections are based on the combination of references. See *In re Keller*, 642 F. 2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F. 2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant argues that Baba describes a very large number of diseases ranging from inflammatory diseases to viral disease. The reference does not specifically disclose HCV infection. Therefore, there is no motivation to select a species from a prior art genus.

This is not persuasive because the Baba reference was merely used to show that nexus between NF-kB inhibitory activity and treatment of viral disease, such as hepatitis. Thus, the rejection was not formulated to select hepatitis from a list of diseases, but was used to show that hepatitis is a disease that is related to NF-kB activity. Examiner notes on the record that the list of diseases is not very large since one of ordinary skill in the art could have readily envisioned this scenario with a reasonable expectation of success.

Applicant argues that Baba merely describes a group of 1,2,3,4-tetrahydroisoquinoline compounds that inhibit NF-kB activity. It does not show whether these NF-kB inhibitors are effective in treating any of the listed diseases, let alone HCV infection. Given the high unpredictability in the medicinal field, it is uncertain as to whether or not HCV infection could be effectively treated by inhibiting NF-kB activity because different NF-kB inhibitors may have totally different effects in treating the same disease. To Applicants' best knowledge, no effective anti-HCV infection drugs have yet been developed via discovering their inhibitory effects on NF-kB activity.

This is not persuasive because although different NF-kB inhibitors may have totally different effects in treating the same disease, the skilled artisan would have reasonably expected that any NF-kB inhibitor would have some positive therapeutic effect even though the degree of therapy may differ. It is Applicant's burden to show factual evidence that a particular NF-kB inhibitor would behave like other NF-kB inhibitors as it relates to treating a particular disease.

A patent shall be presumed valid. Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim. The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity. 35 U.S.C. 282 Presumption of Validity.

Lastly, arguments directed to the Chang Declaration filed on 10/20/09 will not be considered for reasons stated above.